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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/631,613

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Holly Hogrefe

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/631,613

Applicant(s)

HOGREFE ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69, 70, 72 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69, 70, 72, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment filed 10/27/2006 is acknowledged and has been entered. Claims 69 and 72 have been amended. Claims 1-68, 71, 73 and 75-94 have been canceled. Claims 69, 72, and 74 are pending. All of the amendments and arguments have been reviewed and considered but are not found persuasive for the reasons that follow. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This Action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim rejection under 35 USC 112 first paragraph as lacking enablement is withdrawn in view of Applicant's amendment.

New Grounds of Rejection

**THE NEW GROUNDS OF REJECTION WERE NECESSITATED BY
APPLICANT'S AMENDMENT OF THE CLAIMS:**

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 69, 70, 72 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim 69 is drawn to a method of enhancing a nucleic acid polymerase reaction comprising: forming a nucleic acid polymerase reaction composition comprising, (i) a nucleic acid; (ii) at least one nucleic acid polymerase selected from an archaeal nucleic acid polymerase and a modified archaeal nucleic acid polymerase; and (iii) a P45 protein, wherein the P45 protein is in monomeric, dimeric, or multimeric form, and wherein the p45 protein is produced from a cell containing a DNA construct comprising a sequence encoding polymerase enhancing factor protein p45 operably linked to an expression vector, and incubating the nucleic acid polymerase reaction composition under conditions allowing a nucleic acid polymerase reaction, wherein the P45 protein enhances the nucleic acid polymerase reaction. The claim 72 is drawn to a method for controlling the activity of a polymerase in a nucleic acid polymerase reaction, comprising: (a) forming a nucleic acid polymerase reaction composition comprising: (i) a nucleic acid; (ii) at least one nucleic acid polymerase selected from an archaeal nucleic acid polymerase and a modified archaeal nucleic acid polymerase, and (iii) a polymerase enhancing factor activity, wherein the polymerase enhancing factor activity changes the amount of dUTP present or generated during the reaction, and (b) incubating the nucleic acid polymerase reaction under conditions allowing a nucleic acid reaction, wherein changing the amount of dUTP present or generated during the reaction control the activity of the polymerase in the polymerization reaction.

The newly added claim limitation "a modified archaeal nucleic acid polymerase" encompasses a large genus of nucleic acid sequence not adequately

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described or disclosed. The specification teaches at 4, lines 1-4 that "Truncated Taq and T. Flavus DNA polymerase enzymes that apparently exhibit increase thermostability and fidelity in PCR have also been suggested (U.S. Patent 5,436,149)". The specification further teaches that "combinations of polymerases with and without 5' to 3' proofreading activity have also been used (US patent No. 5,489,523)". However, the specification does not teach wherein any truncation of an archaeal nucleic acid polymerase is utilized to determine if it is enhanced in the presence of the p45 protein and/or PEF. Likewise, the specification does not teach or identify wherein any archaeal nucleic acid polymerase that has an altered proofreading function is utilized in the claimed method.

While the specification supports the use of members of the archaeal nucleic acid polymerase family, which includes *Pfu* and Vent DNA polymerases, being effective in the method as claimed, there is no support for the claim as broadly written. The specification does not support the plethora of modification of a nucleic acid polymerase, especially, archaeal nucleic acid polymerases, as encompassed by the claims. Such limitation encompasses *any* nucleic acid change, variation, mutation or functional modification; none of which have been described.

A representative number of nucleic acid species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the modified species as claimed in claims 69, 70,

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72 and 74 of the specification fails to show that Applicant was, in fact "in possession of the claimed invention" at the time the application for patent was filed.

Conclusion

6. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

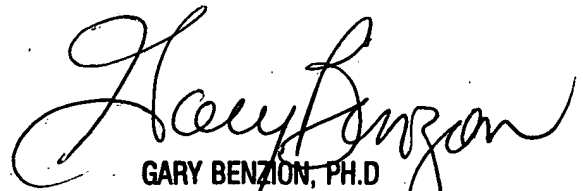
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw



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